

**REMARKS/ARGUMENTS**

**I. Status of the Prosecution and Amendments Made Herein:**

Claims 1-18 were pending and examined in the January 16, 2003 Office Action.

Claims 19-21 had been canceled in response to a Restriction Requirement, as drawn to a non-elected invention. The examiner re-numbered the second claim 14 as claim 15.

The Action noted that the specification should be amended to recite the priority claim and to address informalities with respect to cited references.

Claims 1 and 5-7 have been rejected under 35 U.S.C. §101 as allegedly drawn to non-statutory subject matter. The examiner has indicated that insertion of the term “isolated” before “DNA” would obviate the rejection.

Claims 1-18 stand rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness for the following reasons: (1) lack of clarity of “a modified 3’ UTR being modified so as to be devoid of binding sites for a *dzr1* negative regulatory protein” in claim 1, (2) lack of antecedent basis for “the *dzr1* binding site-containing 3’ UTR” in claim 2, and (3) lack of antecedent basis for “the chimeric gene of claim 11” in claim 18.

Claims 1-18 have been rejected under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description and for alleged lack of enablement. Claim 16, drawn to a plasmid, stands further rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement that would be obviated by a deposit of the plasmid.

Claims 1, 2, 5, 8-10 and 12 have been rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,990,384 to Bagga et al.

Claims 1-3, 5, 8-12 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Bagga et al. in view of Hirt et al. (Curr. Genet., 1990, 17:473-479) and Gordon-Kamm et al. (Plant Cell, 1990, 2:603-618). Claims 1-3, 5-15, 17 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kirihaara et al. (Mol. Gen. Genet. 1998, 211:477-484) in combination with Russell et al. (Trans. Res., 1997, 6:157-168) and Hirt et al. (1990, *supra*).

In accordance with the present amendment, the specification has been amended to include a priority claim and to correct informalities in the citations of certain references. Claims 1-10, 12, 15 and 18 are canceled herein without prejudice. Applicants reserve the right to prosecute the subject matter of the canceled claims in a continuing application. New claims 22-30 have been added. Claim 11 has been amended to call for a method of making high methionine corn seeds that produce saturation levels of 10 kDa zein regardless of the *dzt1* allelic composition of the seed, comprising transforming cells of a corn plant with a vector comprising a chimeric gene encoding a 10 kDa zein, wherein the chimeric gene comprises a 10 kDa zein coding region operably linked at its 5' end to a promoter, and at its 3' end to a heterologous 3' UTR, regenerating fertile transgenic plants from the transformed cells, and producing the high methionine seeds from the plants. Amended claims 13, 14, 16 and 17 and new claims 22-24 are drawn to specific embodiments of the method and transgenic corn plants and their progeny produced by the method. New claims 25-30 are directed to fertile transgenic plants and their progeny that produce high methionine seeds regardless of the *dzt1* allelic composition of the seeds.

Support for the amended and new claims may be found throughout the specification; thus, the amendments and new claims add no new matter to the application. Applicants submit that the rejections of claims 1-18 are not applicable to the claims as amended or to the new claims, and that the claims therefore are in condition for allowance. Support for Applicants' assertion is set forth below.

## **II. The Claims are Directed to Statutory Subject Matter**

Claims 1 and 5-7 dependent thereon stand rejected as allegedly directed to nonstatutory subject matter, i.e., products found in nature. The claims as amended and the new claims are directed to methods of making and using transgenic plants, as well as to transgenic plants and their progeny, thus clearly identifying processes and products not found in nature. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §35 U.S.C. § 101.

## **III. The Claims are Definite**

Claims 1-18 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Claims 1, 2 and 18 were deemed to recite indefinite subject matter. Claims 1, 2 and 18 have been canceled, and the allegedly indefinite phrases do not appear in any other claim as amended, or in any new claim. Applicants assert that all amended and new claims are definite and particularly point out and distinctly claim the subject matter Applicants regard as their invention. Applicants therefore request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

**IV. The Claims are Adequately Described and Enabled by the Specification**

Claims 1-18 have been rejected under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description and for alleged lack of enablement. According to the Action, the specification does not adequately describe or enable practice of the subject matter of claims 1-18 in their full scope. Claims 1-10, 12, 15 and 18 are canceled herein. Claims 11, 13, 14, 16 and 17 have been amended and new claims 22-30 have been added, as described above. Without acknowledging the correctness of the examiner's position with respect to original claims 1-18, Applicants assert that the amended claims and new claims are directed to subject matter that is adequately described and enabled by the specification. Accordingly, withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is requested.

Claim 16, now drawn to a method utilizing a particular vector, stands further rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement that would be obviated by a deposit of the vector. This rejection presumably would also apply to new claim 28, drawn to a transgenic plant comprising a particular vector. Applicants traverse this rejection as it may be applied to the amended and new claims. Construction of Vector pJM2710 is described in Example 1 of the specification. The vector was made by inserting a known 10 kDa zein coding sequence, a known 27 kDa zein promoter and a known 35 S 3' UTR into a known pUC vector. Anyone of skill in the art of plasmid construction could make vector pJM2710 utilizing the information set forth in the specification. Accordingly, the plasmid is obtainable by a repeatable method set forth in the specification, and need not be deposited in order to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is therefore requested.

**V. The Claims are Novel Over the U.S. Patent to Bagga *et al.***

Claims 1, 2, 5, 8-10 and 12 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Bagga *et al.* (U.S. Patent No. 5,990,384). Claims 1-10 and 12 are canceled herein, rendering their rejection moot. Applicants traverse the rejection as it may be applied to the amended and new claims.

The Office Action states that Bagga *et al.* teach fertile transgenic plants that were regenerated from plant cells that were transformed with a vector comprising a DNA construct that comprises the coding sequence of a maize 10 kDa zein operably linked to the CaMV 35S promoter and the NOS terminator. The Office Action further states that Bagga *et al.* also teach seeds and seedlings of the transgenic plant. The Office Action further alleges that plants transformed to express proteins that enhance the protein quality – with improved nutrition for human consumption – can be made with the DNA construct. The Action admits that Bagga *et al.* do not teach transgenic corn plants.

Proof of anticipation (i.e. prior knowledge by others) requires that all of the elements and limitations of the claimed subject matter must be described, expressly or inherently, in a single prior art reference. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988). The single reference must not only describe, but must enable the claimed invention, including all claim limitations, with such clarity and detail as to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)

Bagga *et al.* do not disclose a method of making high methionine corn seeds that produce saturation levels of a 10 kDa zein regardless of the *dzrl* allelic composition of the seeds. Bagga *et al.* do not disclose transgenic corn plants and their progeny that produce high methionine seeds regardless of the *dzrl* allelic composition of the seeds. Therefore, Bagga *et al.* cannot be said to anticipate the invention as presently claimed. Applicants therefore request withdrawal of the rejection under 35 U.S.C. §102(e) on the basis of Bagga *et al.*

#### **VI. The Claims are Not Obvious in View of the Cited References**

Claims 1-3, 5, 8-12 and 18 stand rejected as allegedly unpatentable over Bagga *et al.* in view of Hirt *et al.* and Gordon-Kamm *et al.* The action states that Bagga *et al.* do not teach the CaMV 35S 3' UTR or the transformation of maize, but that Hirt *et al.* teach the use of the CaMV 35S 3' UTR to express foreign genes in different plant species, and Gordon-Kamm *et al.* teaches a method of obtaining stably transformed, fertile maize plants. According to the examiner, it would have been obvious to combine the teachings of Bagga *et al.* with those of Hirt *et al.* and Gordon-Kamm *et al.* to arrive at the invention claimed in claims 1-3, 5, 8-12 and 18.

Claims 1-10, 12 and 18 are canceled herein, rendering their rejection moot. Applicants traverse the rejection as it may be applied to the amended and new claims.

In order for a *prima facie* case of obviousness to be established under 35 U.S.C. §103, there must be a motivation in the art to combine the references identified by the examiner. The prior art must suggest the desirability of the claimed invention. The mere fact the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (MPEP 2143.01).

The invention as presently claimed is directed to production of high methionine corn seed through expression of a 10 kDa zein gene in seeds regardless of the *dzt1* allelic composition of the seeds. Since, prior to the present invention, it was not known that the *dzt1* gene product had a negative regulatory effect on the 10 kDa zein gene, *via* its 3' UTR, there could be no teaching or suggestion in any of the cited prior art references that would motivate their combination to arrive at the presently claimed invention, drawn to a method that solves the problem of negative regulation of the 10 kDa zein gene, and transgenic corn plants and progeny produced by the method, which also comprise the non-obvious feature of expressing the 10 kDa zein gene regardless of the *dzt1* allelic composition of the seeds. Therefore, the invention as claimed is not obvious over the cited combination of references, and withdrawal of the rejection is requested.

Claims 1-3, 5-15, 17 and 18 also stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kiriara *et al.* in view of Russell *et al.* and Hirt *et al.* The Action states that Kiriara *et al.* teach the 10 kDa zein coding region, as well as the fact that the 10 kDa zein contains high methionine and the importance thereof on nutritional quality, but do not teach transgenic maize plants, seed-specific promoters or 3' UTRs. The Action states that Russell *et al.* teach seed-specific promoters such as the 27 kDa zein gene promoter, and the production of fertile transgenic maize plants, and that Hirt *et al.* teach the use of the CaMV 35S 3' UTR to express foreign genes in different plant species. According to the examiner, it would have been obvious to combine the teachings of Kiriara *et al.* with those of Hirt *et al.* and Russell *et al.* to arrive at the invention claimed in claims 1-3, 5-15, 17 and 18.

Claims 1-10, 12, 15 and 18 are canceled herein, rendering their rejection moot. Applicants traverse the rejection as it may be applied to the amended and new claims. As

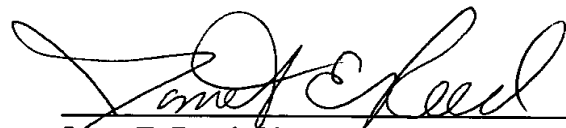
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discussed above, prior to the present invention, it was not known that the *dzr1* gene product had a negative regulatory effect on the 10 kDa zein gene, *via* its 3' UTR. Accordingly, there could be no teaching or suggestion in any of Kiriwara *et al.*, Russell *et al.* or Hirt *et al.* that would motivate their combination to arrive at the presently claimed invention, which is drawn to a method that solves the problem of negative regulation of the 10 kDa zein gene, and transgenic corn plants and progeny produced by the method, which also comprise the non-obvious feature of expressing the 10 kDa zein gene regardless of the *dzr1* allelic composition of the seeds. Therefore, the invention as claimed is not obvious over the cited combination of references, and withdrawal of this rejection is also requested.

In view of the amendments submitted herewith and the foregoing remarks, the presently pending claims are believed to be in condition for allowance. Applicants respectfully request early and favorable reconsideration and withdrawal of the rejections set forth in the January 16, 2003 Official Action, and allowance of this application.

Respectfully submitted,



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